

1 RYAN J. CASAMIQUELA, State Bar No. 228559  
Ryan.casamiquela@apks.com  
2 ARNOLD & PORTER KAYE SCHOLER LLP  
Three Embarcadero Center  
3 San Francisco, CA 94111-4024  
Tel.: (415) 471-3100  
4 Fax: (415) 471-3400

5 MATTHEW M. WOLF (*pro hac vice pending*)  
Matthew.wolf@apks.com  
6 MARC A. COHN (*pro hac vice pending*)  
Marc.cohn@apks.com  
7 ARNOLD & PORTER KAYE SCHOLER LLP  
601 Massachusetts Ave., NW  
8 Washington, DC 20001-3743  
Tel.: (202) 942-5000  
9 Fax: (202) 942-5999

10 *Attorneys for Defendants*  
11 *Hologic, Inc. and Cytoc Surgical Products, LLC*

12 **UNITED STATES DISTRICT COURT**  
13 **NORTHERN DISTRICT OF CALIFORNIA**

14 Minerva Surgical, Inc., a Delaware  
corporation,

15 Plaintiff,

16 vs.

17 Hologic, Inc., a Delaware corporation; AND  
18 Cytoc Surgical Products, LLC, a  
Massachusetts limited liability company,

19 Defendants.  
20

Case No.: 3:17-cv-02013-SK

**ANSWER TO COMPLAINT FOR  
PATENT INFRINGEMENT AND  
COUNTERCLAIMS**

**ANSWER**

Defendants Hologic, Inc. (“Hologic”) and Cytac Surgical Products, LLC (“Cytac”) (collectively “Defendants”) hereby respond to the allegations in the Complaint of Plaintiff Minerva Surgical, Inc. (“Plaintiff” or “Minerva”) as follows. Except as otherwise specifically admitted, qualified, or denied herein, all allegations of the Complaint are denied.

**NATURE OF THE ACTION**

1. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants acknowledge that the Complaint purports to bring a civil action for patent infringement. Defendants deny any other allegations in this paragraph.

**THE PARTIES**

2. On information and belief, Defendants admit that Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA 94063.

3. Defendants admit the allegations in Paragraph 3 of the Complaint.

4. Defendants admit the allegations in Paragraph 4 of the Complaint.

**JURISDICTION AND VENUE**

5. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants acknowledge that this Court has subject matter jurisdiction over the cause of action asserted in the Complaint, but denies that there is any factual or legal basis for Minerva’s claims.

6. This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not dispute that personal jurisdiction is proper in this District for purposes of this action, but deny that Defendants have committed any acts of patent infringement.

7. Defendants admit that they sell the NovaSure® ADVANCED device in the United States and in this District. Defendants deny any other allegations in this paragraph.

1           8.       Defendants admit that *Hologic, Inc. et al. v. SenoRx, Inc.*, Case No. 5-08-cv-00133,  
2 was a prior litigation in the Northern District of California. Defendants deny any other allegations  
3 in this paragraph.

4           9.       This paragraph states legal conclusions to which no response is required. To the  
5 extent a response is required, Defendants do not dispute that venue is proper in this District for  
6 purposes of this action, but deny that they have committed any acts of patent infringement.

7                               **INTRADISTRICT ASSIGNMENT**

8           10.      This paragraph contains statements to which no response is required.

9                               **BACKGROUND**

10          11.      Defendants admit that the endometrium can sometimes be the source of abnormal  
11 uterine bleeding in women and that this condition is sometimes referred to as menorrhagia or heavy  
12 menstrual bleeding. Defendants admit that over 10 million women in the United States suffer each  
13 year from menorrhagia, which can lead to, among other things, iron deficiency and severe anemia.  
14 Defendants deny any remaining allegations in Paragraph 11 of the Complaint.

15          12.      Defendants admit that Minerva's business is to develop, manufacture, and supply a  
16 medical endometrial ablation device for treating menorrhagia, and that this device is called the  
17 Minerva® Endometrial Ablation System. Defendants lack information sufficient to form a belief as  
18 to the remaining allegations in Paragraph 12 of the Complaint and on that basis denies those  
19 allegations.

20          13.      Defendants admit that the Minerva® Endometrial Ablation System ablates the  
21 endometrium. Defendants admit that the Minerva® Endometrial Ablation System deploys an array  
22 at the distal end of the system's disposable handpiece. Defendants admit that the Minerva®  
23 Endometrial Ablation System uses radio frequency (RF) electric current. Defendants admit that the  
24 Minerva® Endometrial Ablation System contacts the tissue directly. Defendants admit that the  
25 system uses a silicone membrane at the distal end of the Minerva handpiece. Defendants deny the  
26 remaining allegations in this paragraph.

14. Defendants admit that a copy of Minerva's Summary of Safety and Effectiveness Data (SSED) is attached to the Complaint at Exhibit A. Defendants deny the remaining allegations of Paragraph 14 of the Complaint.

15. Defendants admit that a copy of U.S. Patent No. 9,186,208 ("the '208 Patent") is attached to the Complaint at Exhibit B. Defendants deny the remaining allegations of Paragraph 15 of the Complaint.

16. Defendants admit that they have been directly competing with and continue to directly compete with Minerva. Defendants admit that they have been offering for sale and selling the NovaSure ADVANCED device since February 2017. Defendants admit that a copy of the NovaSure ADVANCED Instructions for Use is attached to the Complaint at Exhibit C. Defendants deny the remaining allegations of Paragraph 16 of the Complaint.

17. Defendants admit that the NovaSure ADVANCED device is advertised for endometrial ablation. Defendants deny the remaining allegations of Paragraph 17 of the Complaint.

18. Defendants deny the allegations in Paragraph 18 of the Complaint.

19. Defendants deny the allegations in Paragraph 19 of the Complaint.

### **CLAIMS FOR RELIEF**

#### **(Defendants' Direct and Indirect Infringement of the '208 Patent)**

20. Defendants incorporate by reference its answers to the allegations in Paragraphs 1 through 19 of the Complaint as though fully set forth herein.

21. Defendants admit that the '208 Patent is entitled "Systems for Endometrial Ablation" and that it was issued on November 17, 2015. Defendants deny the remaining allegations of Paragraph 21 of the Complaint.

22. Defendants admit that a copy of the '208 Patent is attached to the Complaint at Exhibit B. Defendants deny the remaining allegations of Paragraph 22 of the Complaint.

23. Defendants lack information sufficient to form a belief as to the truth of the allegations in Paragraph 23 of the Complaint and on that basis denies the allegations.

24. Defendants deny the allegations in Paragraph 24 of the Complaint.

25. Defendants deny the allegations in Paragraph 25 of the Complaint.

26. Defendants deny the allegations in Paragraph 26 of the Complaint.

27. Defendants deny the allegations in Paragraph 27 of the Complaint.

28. Defendants deny the allegations in Paragraph 28 of the Complaint.

**PRAYER FOR RELIEF**

A. Defendants deny that Minerva is entitled to the relief requested in paragraph A of the Complaint.

B. Defendants deny that Minerva is entitled to the relief requested in paragraph B of the Complaint.

C. Defendants deny that Minerva is entitled to the relief requested in paragraph C of the Complaint.

D. Defendants deny that Minerva is entitled to the relief requested in paragraph D of the Complaint.

E. Defendants deny that Minerva is entitled to the relief requested in paragraph E of the Complaint.

**DEMAND FOR JURY TRIAL**

Defendants hereby demand a trial by jury on all issues so triable.

**AFFIRMATIVE DEFENSES**

Further to answering the Complaint, Defendants assert the following defenses. Defendants reserve the right to amend this answer with additional defenses as further information is obtained.

**FIRST DEFENSE  
(Failure to State a Claim)**

1. Minerva's Complaint and each Count therein fails to state a claim upon which relief can be granted.

**SECOND DEFENSE  
(Noninfringement)**

2. Defendants do not infringe and have not infringed, either directly or indirectly, do not and have not induced infringement, and do not and have not contributed to the infringement of,

1 at least the claim of the '208 Patent identified in Minerva's Complaint, either literally or under the  
2 doctrine of equivalents.

3 **THIRD DEFENSE**  
4 **(Invalidity)**

5 3. The Patent-in-Suit is invalid, including at least the asserted claim, for failure to meet  
6 the conditions of patentability set forth in 35 U.S.C. §§ 102, 103, and/or 112. To the extent that  
7 Minerva should later seek to assert additional claims of the Patent-in-Suit, Defendants reserve the  
8 right to assert that any such additional asserted claims are also invalid.

9 **FOURTH DEFENSE**  
10 **(Patent Unenforceability / Limitation on Patent Scope)**

11 4. Minerva's claims are barred in whole or in part by the doctrines of waiver and/or  
12 estoppel, including prosecution history estoppel and/or equitable estoppel.

13 **FIFTH DEFENSE**  
14 **(Limitation on Patent Damages)**

15 5. Minerva's claim for damages, if any, against Defendants for alleged infringement are  
16 limited by 35 U.S.C. § 287 and/or § 288, including, for example, based on the failure to mark the  
17 '208 Patent.

18 **SIXTH DEFENSE**  
19 **(Unclean Hands)**

20 6. Minerva's claims are barred by the doctrine of unclean hands, including without  
21 limitation, by Minerva's filing of this retaliatory lawsuit in bad faith and by making false and  
22 misleading statements related to Hologic's NovaSure products.

23 **COUNTERCLAIMS**

24 Defendants allege the following counterclaims against Minerva:

25 **PARTIES**

26 1. Counterclaim-Plaintiff Hologic is a corporation organized and existing under the  
27 laws of the State of Delaware with a principal place of business at 250 Campus Drive,  
28 Marlborough, Massachusetts 01752.

3. On information and belief, Counterclaim-Defendant Minerva is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 101 Saginaw Drive, Redwood City, CA 94063.

## **JURISDICTION AND VENUE**

4. This action for declaratory relief arises under the Declaratory Judgment Act, 28 U.S.C. §§2201 and 2202.

5. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338.

6. Minerva is subject to personal jurisdiction in this judicial district because it availed itself of the jurisdiction of this Court and engaged in acts giving rise to this controversy in this district.

7. Venue in this District is proper pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

## COUNT I

**(Declaratory Judgment of Noninfringement of the '208 Patent)**

8. Hologic and Cytac restate, reallege and incorporate by reference the allegations made in the foregoing paragraphs.

9. Minerva alleges that it is the owner of all rights, title, and interest in the '208 Patent.

10. Minerva alleges that Hologic and Cytac infringe at least one claim of the '208 Patent.

11. Hologic and Cytac deny that they have been or are infringing, directly or indirectly, any valid claim of the '208 Patent.

12. An actual controversy exists between Hologic and Cytac on the one hand, and Minerva on the other, regarding the alleged infringement of the asserted claim of the '208 Patent.

13. Accordingly, Hologic and Cytac are entitled to a declaratory judgment that they have not and do not infringe the '208 Patent.

**COUNT II**

**(Declaratory Judgment of Invalidity of the '208 Patent)**

14. Hologic and Cytac restate, reallege and incorporate by reference the allegations made in the foregoing paragraphs.

15. Minerva alleges that it is the owner of all rights, title, and interest in the '208 Patent.

16. The asserted claim of the '208 Patent is invalid because it fails to comply with one or more requirements of United States Code Title 35, including, without limitation, one or more requirements of 35 U.S.C. §§ 102, 103 and/or 112.

17. An actual controversy exists between Hologic and Cytac on the one hand, and Minerva on the other, regarding the invalidity of the asserted claim of the '208 Patent.

18. Accordingly, Hologic and Cytac are entitled to a declaratory judgment that the asserted claim of the '208 Patent is invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Hologic and Cytac request the following relief:

A. That this Court enter judgment against Minerva and in favor of Hologic and Cytac on the claims set forth in Minerva's Complaint and that each such claim be dismissed with prejudice;

B. That this Court enter judgment that any asserted claim of the '208 Patent is invalid;

C. That this Court enter judgment that Hologic and Cytac have not and do not infringe, directly or indirectly, any valid claim of the '208 Patent, either literally or under the doctrine of equivalents;

D. That this Court declare this to be an exceptional case under 35 U.S.C. § 285 and award Hologic and Cytac their costs and expenses, including reasonable attorneys' fees; and

E. That this Court grant Hologic and Cytac such other relief as the Court deems just and proper.

**DEMAND FOR JURY TRIAL**

Hologic and Cytac hereby demand a trial by jury on all issues so triable.



1 Dated: May 4, 2017

ARNOLD & PORTER KAYE SCHOLER LLP

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3  
4 By: /s/ Ryan J. Casamiquela

5 *Attorneys for Defendants Hologic, Inc. and*  
6 *Cytac Surgical Products, LLC*  
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